DETAILED ACTION

1. Applicants' arguments, filed December 15, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 3 – 5 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/795792 in view of Alderman (US 4,734,285). As Application 11/795792 has gone abandoned since the mailing date of the previous Office Action in this case, this rejection is WITHDRAWN.

Response to Amendment

4. The declaration under 37 CFR 1.132 filed December 15, 2009 is insufficient to overcome the rejection of claims 3 - 5 based upon Baichwal in view of Miyachi et al. and Alderman as set forth in the last Office action because: the claims are not commensurate in scope with the evidence presented in the declaration.

Clarification is also requested as to how the three methods tested by applicant correspond with the methods presented in Alderman. Page 2 of the declaration indicates that the methods were exemplified by Alderman. The Examiner was unable to determine how these three methods correspond with those used in Alderman.

Also, the description of the methods set forth for the direct compression method and dry granulation method are somewhat unclear. The initial mixing steps set forth in the declaration are the same for these two methods. In these steps, it is unclear if additional ingredients were added to each trituration sequentially. For example, was 9 g + 90 g+ 68 g of pregelatinized starch used in the mixture that was compressed? If so, the proportions of the ingredients (e.g., starch to HPMC or starch to KRP-127) do not appear to match those set forth in table 1 of the declaration. What occurs in each of these step is unclear.

Additional explanation or clarification of these points is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 3 – 5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal (US 5,399,359) in view of Miyachi et al. (Bioorganic & Medicinal Chemistry 1999) and Alderman (US 4,734,285). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed June 16, 2009 and those set forth below.

Applicant traverses the general and unsupported assertion that the invention may be easily achieved by merely applying the sustained release techniques disclosed by Alderman to the teachings of the other two references. When a very small amount of

active ingredient is to be contained in a sustained release tablet such as in Applicant's invention, it is remarkably difficult to make uniform pharmaceutical tablet by direct compression, dry granulation or wet granulation. The experiments performed and data set forth in the declaration demonstrate that the content uniformity of the tablets prepared according to the prior art direct compression method, dry granulation and wet granulation was poor because of remarkable variation. The content uniformity of the tablets prepared in accordance with Example 5 was favorable. The fundamental problem to be solved cannot be achieved by merely applying the technique of Alderman to these known techniques as Alderman does not disclose or suggest any essential feature of Applicants' invention.

These arguments and evidence are unpersuasive. Claims 3 – 5 are composition claims. Claim 3 has no limitations as to how the composition is prepared. Therefore, this claim encompasses compositions made by any process, including those of the prior art.

Claims 4 and 5 include some process limitations - manufacturing a granular composition by spraying a solution of KRP-197 on partly pre-gelatinized starch to achieve a uniform dispersion of KRP-197 by means of a fluidized bed granulation method. That granular composition is then mixed with a composition containing the hydroxypropylmethycellulose. However, the method used in example 5 requires the presence of additional pregelatinized starch and magnesium stearate when the HPMC is mixed with the KRP-127/partly pregelatinized starch granules. The data presented in the declaration is not commensurate in scope with the claims. The correlation between the methods of the closest prior art and those recited in the declaration are unclear.

Due to the confusion that exists for the correspondence between the methods of the cited prior art and the methods used in the declaration and that the evidence presented in the specification is not commensurate in scope with the instant claims, this rejection is maintained.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW